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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/848,774
Filing Date: May 03, 2001
Appellant(s): GONDA ET AL.

Scott T. Weingaertner
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 05/10/2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The amendment after final rejection filed on 05/10/2004 has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 22,23,25,26,31,35 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,192,548 VELASQUEZ ET AL. 3-1993

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22, 23,25,26,31,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schenk et al. (WO 90/07351) in view of Velasquez et al. ('548).

As to claim 22, Schenk et al. disclose a method of treating a patient comprising the steps of: supplying a predetermined amount of dry powder (11) to an inhalation device; releasing a pressurized gas (figs.1-6) over a predetermined amount of dry powder to create an aerosolized suspension (16) comprising powder suspended in air; and inhaling the aerosolized suspension at a flow rate and volume sufficient to allow the patient to absorb in the bloodstream a controlled dose of medicament.

The differences between Schenk et al. and claim 22 are insulin as the dry powder medicament and the recited intended result of the insulin containing 2-10 times higher the amount needed to be absorbed in the blood stream of a patient and the intended result of 1-50 units of insulin being absorbed into a patient's bloodstream.

Velasquez et al. teach a variety of dry powder medicaments as inhalable powders including insulin as a dry powder medicament for inhalation by a patient.

It would have been obvious to modify the dry powder in Schenk et al. to employ dry powder insulin as the medicament because it would have provided an easy and painless manner of delivering insulin to patients as taught by Velasquez et al..

As to the recited intended result of the amount of insulin employed and the amount of insulin being absorbed, it is submitted that the amount of insulin employed and the amount absorbed can be arrived at through mere routine obvious experimentation and observation. That is, the amount of insulin stored in the inhalation device and the amount being absorbed would vary in dependence upon the age, sex and severity of the diabetes of the patient being treated. Consequently, one of ordinary skill would realize that the amount stored and absorbed would need to be tailored to the particular patient's medical needs.

As to claim 23, inasmuch as Schenk et al. as modified by Velasquez et al. teach a method and device for treating diabetes, is stands to reason that the administration protocol would have included repeated inhalation (administration) of insulin to maintain an adequate concentration of medicament in a patient's bloodstream.

As to claim 25, Schenk et al. as modified by Velasquez et al. as discussed above also teach flowing at least a portion of the aerosolized suspension through a mouthpiece (20) on the device and into the patient's lungs in a manner sufficient to cause the patient to absorb a controlled quantity of insulin.

As to claim 26, inasmuch as Schenk et al. as modified by Velasquez et al. teach a method and device for treating diabetes, is stands to reason that the administration

protocol would have included repeated inhalation (administration) of insulin to maintain an adequate concentration of medicament in a patient's bloodstream.

Claims 31,35 are substantially equivalent in scope to claims 22,23,25,26 and are included in Schenk et al. as modified by Velasquez et al. for the reasons set forth above with respect to claims 22,23,25,26.

As to the recited claimed limitations defining a controlled quantity of insulin which is sufficient to achieve the desired result, Schenk et al. (page 3, lines 5-3; page 4, line 27-37) disclose a device which maximizes the amount of aerosolized powder medicament thereby facilitating maximum amounts of medicament inhaled and absorbed into a patient's bloodstream. That is, given that Schenk et al. disclose aerosolizing most of the medicament within the aerosolization chamber (16), the amount of medicament available for inhalation by a patient is predictable.

(11) Response to Argument

As pointed in the summary of the invention hereinabove, the instant (claimed) invention defines a method of treating diabetes mellitus through the controlled inhalation of insulin powder.

Extrinsic evidence to support the positions taken in the rejection above is taken from Harrison's Principles of Internal Medicine, 13th edition, vol.2, pp.1986-1987 is as follows: A patient suffering from this disease presents symptoms including an abnormally high concentration of blood glucose; accordingly, the purpose of a treatment regimen is to bring the concentration of blood glucose back to a value that is within a "normal" range of blood glucose concentration values. In an effort to achieve the goal of "normal" blood

glucose a physician typically prescribes the administration of insulin. The quantity of insulin that is administered to patients is defined in Units of insulin. Factors which physicians into account when determining how many units of insulin to administer to a given patient include a patient's age and body weight (e.g. adults of normal weight may be started on 15-20 units a day); however, the administered amount is typically adjusted when significant extra activity or exercise is anticipated.

Appellant's assertion that the PTO has not established a prima facie showing of obviousness based upon Schenk et al. in view of Velasquez et al. and in light of known treatment for diabetes mellitus with insulin is not persuasive. The propriety of the prior art combination is not based upon an "obvious to try" motivation; rather it is based upon the substitution of powdered insulin for the powdered medicament which is administered using the inhaler of Schenk et al.. Additionally, one of ordinary skill would also recognize that any powdered insulin administered using the inhaler of Schenk et al. as modified by Velasquez et al. must be administered to patients under known guidelines of standard medical practice in the treatment of diabetes mellitus.

Appellant's argument that a treatment for diabetes mellitus is not implicit in the administration of powdered insulin using the inhaler of Schenk et al. as modified by Velasquez et al. is not accurate because the use of the prior art inhaler to administer powdered insulin would necessarily result in and would be exemplary of a treatment method for diabetes mellitus by the administration of insulin.

Appellant's argument alleging a lack of express disclosure of an "effective amount" of insulin being delivered to a patient is disagreed with because one of ordinary skill (i.e. a

physician since insulin is prescription medicine) would realize the absolute criticality for administering an amount of insulin that would effectively bring a patient's blood glucose values into a "normal" range. While the prior art combination may not expressly disclose a particular amount one of ordinary skill being equipped with known medical guidelines for treatment of diabetes mellitus would know to make adjustments in the quantity of powdered medicament in order to provide a dose which would effectively bring a patient's blood glucose within a "normal" range.

As to appellant's arguments regarding the claimed dose of insulin (i.e. 1-50 units of insulin), one of ordinary skill would realize the need to administer sufficient powdered insulin to bring a diabetic patient's blood glucose within a "normal" range. Such a dose amount can be arrived at through mere routine obvious experimentation and observation in dependence upon patient's age and weight; moreover, extrinsic evidence above shows that an adult of normal weight is started on 15-20 units per day. Finally, a review of the instant specification reveals no criticality for a dose of insulin being 1-50 units.

As to appellant's arguments regarding the claimed amount of insulin in the aerosolized suspension being 2-10 times higher than the amount needed to be absorbed in the bloodstream, it is submitted that the amount of any aerosolized medicament in any inhaler would need to exceed that which is intended to be absorbed into a patient's bloodstream due to known losses of medicament to internal surfaces of the inhaler, losses of medicament to nasal cavities, inside surfaces of a patient's mouth, the back of a patient's throat. Extrinsic evidence to support these losses as well known

to one of ordinary skill is found in Laube et al. U.S. Patent 5,320,094 at col.5, lines 35-48. Finally, a review of the instant specification reveals no criticality for the amount of insulin in the aerosolized suspension being 2-10 times higher than the amount needed to be absorbed into a patient's bloodstream.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
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Aaron J. Lewis
January 25, 2006

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